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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,071

09/13/2005

Pascal Bernard

0579-1082

5118

466

7590

07/02/2009

YOUNG & THOMPSON

209 Madison Street

Suite 500

ALEXANDRIA, VA 22314

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

07/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,071	<b>Applicant(s)</b> BERNARD ET AL.	
	<b>Examiner</b> Adam Marcetich	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. France 0208467, filed on 05 July 2002 has been received.

### ***Claim Interpretation***

2. Examiner finds an enabling description of the invention and interprets amended claims 1 and 11 in light of the specification.

3. Regarding claims 1 and 11, the specification supports:

[1,11] a meatal occluder for closing a lachrymal meatus of a human eye, comprising a substantially cylindrical body (p. 4, lines 6-14, Figs. 1-5, cylindrical body 10) and

[1,11] at least one fin (p. 4, lines 27-30, Figs. 1-5, fins 13)

[1,11] adapted to take up a folded position (p. 4-5, lines 31-1);

[1,11] wherein the fin is substantially folded into a reduced diameter portion of the cylindrical body p. 4-5, lines 31-1, p.6, lines 20-23, p. 6-7, lines 32-1, Figs. 1B, 2B, 3B, 4B, 5B, reduced diameter portion 10'); and

[1,11] wherein the fin comprises a free end, said free end being substantially housed into a reduced diameter portion of the cylindrical body, when the fin is in said folded position (Figs. 1B, 2B, 3B, 4B, 5B, fins 13 having free end fitting into reduced diameter portions 10');

[11] wherein the cylindrical body and the at least one fin are constructed and arranged so that exposure of the heat deformable material to a heating effect of a human body causes the at least one fin to move from the first position of being arranged substantially parallel to the longitudinal axis to a second position in which the at least one fin extends outward from the longitudinal axis, wherein when the at least one fin is in the first position, an exterior of the fin is arranged so as to preserve the cylindrical shape of the cylindrical body (p. 7, lines 27-29, Fig. 5B); and

### ***Claim Objections***

4. Claim 11 is objected to because of the following informalities: Applicant has amended claim 11 to include the language ". . . when the fin is in said folded position. . ." However, claim 11 contains only first and second positions. Examiner interprets the claimed ". . . folded position. . ." as a first position, and recommends amending claim 11 as ". . . when the fin is in said first position. . ." for proper antecedent basis.
5. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

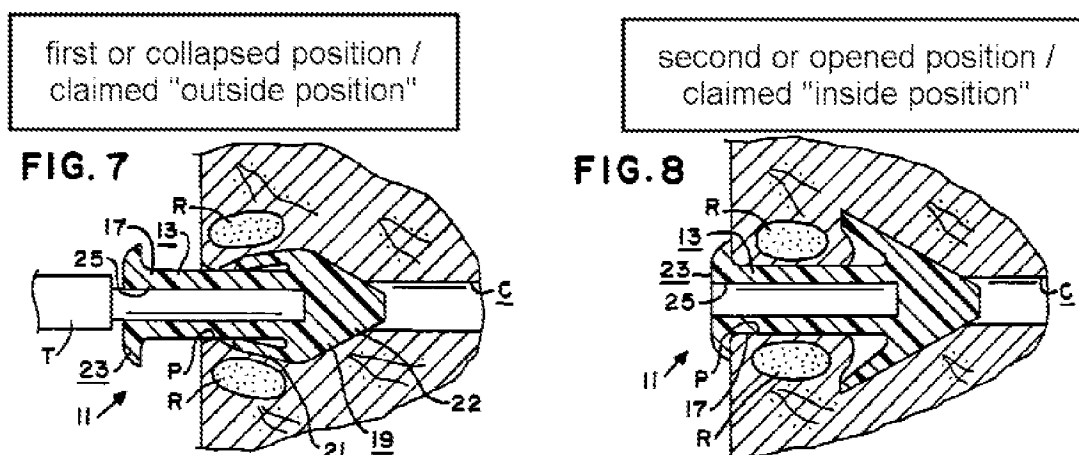
8. Claims 1-7, 9, 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace; Raymond G. (US 5830171) in view of Thompson; Bruce R. (US 4312612).

9. Regarding claims 1 and 20, Wallace discloses a punctal occluder (col. 2, lines 29-37) adaptable for use as a meatal occluder of a human eye, comprising:

[1] a substantially cylindrical body (column 3, lines 50-54 and Figs. 1-3, shank 13) characterized in that it further comprises:

[1] at least one fin adapted to take up an outside position outside the lachrymal meatus wherein the fin is substantially folded into the cylindrical body (column 3, lines 55-64, especially lines 60-61 and Fig. 7, wing portion 21 having a first collapsed position, see annotated figure below. Regarding the limitation of being outside the lachrymal meatus, it is the Examiner's position that wing portion 21 of Wallace may be placed within a different physiological lumen, or held in its folded position manually or by deployment means.); and

[1] an inside position into the lachrymal meatus wherein the fin projects from the cylindrical body (col. 3, lines 64-67, especially lines 64-65 and Fig. 8, wing portion 21 having second expanded position, see annotated figure below).



Annotated Figs. 7, 8 of Wallace

[1] Examiner notes that Wallace uses the same material, silicone (col. 5, lines 8-13) as disclosed in the immediate specification (p. 8, lines 1-5, especially line 2), therefore the material used by Wallace is fully capable of being heat-deformable as claimed [claim 1].

Wallace discloses the invention substantially as claimed, see above. However, Wallace lacks free ends housed in a reduced diameter portion as claimed [claims 1 and 20]. Thompson discloses a screw fixing device and plug for insertion in an aperture (col. 1, lines 5-11, col. 2, lines 28-33, Figs. 1-6, screw fixing device) further comprising:

[1] a substantially cylindrical body (Figs. 1-4, device having cylindrical body);

[1] at least one fin adapted to take up a folded position (col. 2, lines 35-41, Figs. 1-4, wings 6);

[1, 20] wherein the fin is substantially folded into a reduced diameter portion of the cylindrical body (col. 2, lines 42-55. especially lines 46-49, Fig. 4, wings 6 folding into recesses near tapered surfaces 8);

[1, 20] and an extended position wherein the fin projects from the cylindrical body (col. 2, lines 42-55. especially lines 46-49, Figs. 2, 3, wings 6 projecting from recesses near tapered surfaces 8); and

[1, 20] wherein the fin comprises a free end (col. 2, lines 42-55, especially lines 46-49, Figs. 1-3, free ends 7);

[1, 20] said free end being substantially housed into a reduced diameter portion of the cylindrical body, when the fin is in said folded position (Fig. 4, free ends 7 housed near tapered surfaces 8);

[20] wherein when the fin is in the folded position the fin is substantially folded into a reduced diameter portion of the cylindrical body so as to preserve the cylindrical shape of the cylindrical body (Fig. 4, folded wings 6 preserving cylindrical shape of cylindrical body).

Thompson reduces the diameter of a fixation device inserted into an aperture (col. 1, lines 30-44, especially lines 57-62, wings displaced inwardly when inserting device into aperture). Both Wallace and Thompson place a cylindrical fixing device with expanding fins into an aperture to anchor it. While Thompson fixes panels together and is not implanted in living tissue, a person having ordinary skill in the art would reasonably expect similar results from a fixing device having a reduced diameter portion. That is, reducing the diameter of a fixing device eases insertion. Wallace calls

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for an implant that is easy to insert (col. 6, lines 5-9, especially line 7), therefore one would have been motivated to modify Wallace with the reduced diameter portions of Thompson.

10. Regarding claims 2 and 3, Wallace discloses a meatal occluder characterized in that it is made from silicone (col. 5, lines 8-13). Examiner notes that silicone is a heat-expandable material, since it is capable of expanding when heated. In other words, the language "heat-expandable" is being interpreted to include materials that expand when heated, such as silicone. Additionally, Applicant discloses silicone as a suitable heat-expandable material for forming the implant (immediate specification, p. 7-8, lines 35-5, especially line 2 and lines 11-15, especially line 13, "silicones"). Therefore, Examiner interprets the silicone material of Wallace as anticipating the claimed heat-expandable material.

11. Regarding claim 4, Wallace discloses the invention as substantially claimed, including silicone as discussed above. The specification of the immediate application discloses silicone as a polymer capable of having a vitreous transition temperature from -10°C to 30° (p. 8, lines 11-15). Therefore, the property of vitreous transition temperature is an intrinsic property of the materials used, and the device of Wallace is capable of having a vitreous transition temperature from -10°C to 30°C.

12. Regarding claim 5, Wallace discloses a meatal occluder characterized in that said fin pivots between said folded position and said extended position about an axis perpendicular to a longitudinal plane of said meatal occluder (col. 4, lines 35-42 and



Figs. 7 and 9, wing portion 21 pivoting about axis perpendicular to longitudinal plane of shank 13).

13. Regarding claim 6, Wallace depicts a meatal occluder characterized in that said fin when in said folded position extends in a direction substantially parallel to the longitudinal direction of the cylindrical body (Fig. 7, wing portion 21 extending substantially parallel to shank 13).

14. Regarding claim 7, Wallace depicts a meatal occluder characterized in that said fin is situated in the vicinity of one end of said cylindrical body, a free end of said fin, when in the folded position, extending in the direction of the opposite end of said cylindrical body (Fig. 9, end of wing portion 21 having folded position extending in direction opposite of shank 13).

15. Regarding claim 9, Wallace discloses a meatal occluder characterized in that said fin is situated in the vicinity of a tapered end of said cylindrical body, the opposite end of said cylindrical body comprising a flange (column 4, lines 22-24 and 43-49; Figs. 2 and 3, flange 23 near nose portion 22).

16. Regarding claim 10, Wallace discloses a meatal occluder characterized in that it comprises a plurality of fins regularly distributed on the cylindrical body of said occluder (col. 4, lines 22-24, "wing portion 21 may be formed by a plurality of individual wing elements").

17. Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace; Raymond G. (US 5830171) in view of Hirohata; Toshio (US 4668145).

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18. Regarding claims 11 and 17, Wallace discloses a punctal occluder (col. 2, lines 29-37), adaptable for use as a meatal occluder of a human eye, as discussed for claims 1 and 20 above. However, Wallace lacks a fin extending from the cylindrical body substantially parallel to the longitudinal axis, and positioned to extend and pivot as claimed [claims 11 and 17].

Hirohata discloses a fastener for coupling panels (col. 1, lines 5-11, (col. 2, lines 56-63, Figs. 2-5, female member 2); further comprising:

[11] a substantially cylindrical body having a longitudinal axis (col. 2, lines 56-63, Figs. 2-5, locking body portion 6);

[11] at least one fin (col. 2, lines 56-63, Figs. 2-5, locking pawl portions 7);

[11] the at least one fin having a first position in which the at least one fin extends from the cylindrical body substantially parallel to the longitudinal axis (col. 3, lines 37-46, especially lines 45-46, Figs. 4, 5, locking pawl portions 7 folded inside recesses 13);

[11, 17] wherein the fin moves and pivots from the first position of being arranged substantially parallel to the longitudinal axis to a second position in which the at least one fin extends outward from the longitudinal axis (col. 3, lines 45-46, Figs. 4, 5, locking pawl portions 7 flexed out of recesses 13);

[11] wherein when the at least one fin is in the first position, an exterior of the fin is arranged so as to preserve the cylindrical shape of the cylindrical body (Figs. 4, 5, locking pawl portions folding inside diameter of locking body portion 6); and

[11] wherein the fin comprises a free end (col. 3, lines 37-46, Figs. 4, 5, locking pawl portions 7 having free ends near arcuate edge 12);

[11] said free end being substantially housed into a reduced diameter portion of the cylindrical body, when the fin is in said first position (col. 3, lines 52-62, locking pawl portions 7 inwardly flexed into recesses 13);

Hirohata eases the insertion of a cylindrical fastening member (col. 5, lines 19-28, especially lines 23-24, recesses enhancing insertion property). One would be motivated to modify Wallace with the recessed portions of Hirohata to improve an insertion property since Wallace calls for an easily inserted implant as discussed for claims 1 and 20 above. Here also, Hirohata applies to the problem of fixing a cylindrical body within an aperture using flexing fins or wings.

19. Regarding claims 12, 13, 14, 15, 16, 18 and 19, see discussion of claims 2, 3, 4, 5, 7, 9 and 10 above, respectively.

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent 5,830,171) in view of Thompson; Bruce R. (US 4312612), further in view of Fouere (US Patent 6,254,562).

21. Regarding claim 8, Wallace in view of Thompson discloses the invention as substantially claimed; see discussion of claims 1 and 20 above. However, Wallace in view of Thompson lacks a fin pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of a cylindrical body as claimed [claim 8]. Hirohata discloses fins that pivot about an axis parallel to the longitudinal direction of a cylindrical body, as discussed for claims 11 and 17 above.

See discussion of claims 11 and 17 above regarding rationale and motivation to modify Wallace and Thompson in view of Hirohata.

### ***Response to Arguments***

22. Applicant's arguments, see p. 8-10 filed 13 April 2009 with respect to the rejection(s) of claim(s) 1-20 under 35 USC § 103 over Wallace, Roschak and Fouere have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Wallace, Thompson and Hirohata.

23. Applicant contends that the expansion of hinged member 352 of Roschak cannot be applied to a fin projecting from the cylindrical body of the lachrymal meatus, as a fin has one free end which is not fixed to the cylindrical body. Examiner has withdrawn the rejection over Wallace in view of Roschak, and cites Thompson as teaching a free end in the new grounds of rejection.

24. Applicant asserts that each of Roschak, Wallace and Fouere lack a deformable fin with a free end folded into a reduced diameter portion of the cylindrical body. Examiner cites Thompson and Hirohata as teaching deformable fins with a free end folded into a reduced diameter portion in the new grounds of rejection. Additionally, Examiner cites Hirohata as teaching deformable fins that pivot about an axis parallel to the longitudinal direction of a cylindrical body.

### ***Conclusion***

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

◆ Kurosaki; Mutsuo	US D273091
◆ Rapata; George M.	US 3093874
◆ Meyer; Engelbert A.	US 3693494
◆ Murphy; Colin	US 5049018
◆ Oettl; Reinhold	US 4609316
◆ Nakama; Daiji et al.	US 4704059
◆ Kazino; Hiroshi et al.	US 4579492

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

27. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/  
Examiner, Art Unit 3761

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
1 July 2009